Chapter 3
Section 1.6E

COMBINED LIVER-KIDNEY TRANSPLANTATION

Issue Date: October 26, 1994 Authority: 32 CFR 199.4(e)(5)

I. PROCEDURE CODE RANGE

47150

II. POLICY

A. Preauthorized benefits are allowed for combined liver-kidney transplantation (CLKT).

- 1. A TRICARE Prime enrollee must have a referral from his/her Primary Care Manager (PCM) and an authorization from the Health Care Finder (HCF) before obtaining transplant-related services. If network providers furnish transplant-related services without prior PCM referral and HCF authorization, penalties will be administered according to TRICARE network provider agreements. If Prime enrollees receive transplant-related services from non-network civilian providers without the required PCM referral and HCF authorization, Managed Care Support (MCS) contractors shall reimburse charges for the services on a Point of Service basis. Special cost-sharing requirements apply to Point of Service claims. For specific information on Point of Service cost-shares and catastrophic cap calculations, see Chapter 12, Section 2.2, and Section 10.1, and Chapter 13, Section 14.1.
- 2. For Standard and Extra patients residing in a Managed Care Support (MCS) region, preauthorization authority is the responsibility of the MCS Medical Director, Health Care Finder, or other designated utilization staff.
- B. The designated preauthorizing authority shall only use the criteria contained in this policy when preauthorizing combined liver-kidney transplantation.
- C. <u>Affirmative Patient Selection Criteria</u>. Benefits may be allowed for medically necessary services and supplies related to CLKT when the transplant is performed at a TRICARE or Medicare approved liver transplant center, for beneficiaries who:
 - 1. Are suffering from concomitant, irreversible hepatic and renal failure; and
- 2. Have exhausted more conservative medical and surgical treatments for hepatic and renal failure.

- 3. Have plans for long-term adherence to a disciplined medical regimen that are feasible and realistic.
- D. Transplants performed for beneficiaries suffering from hepatic failure resulting from hepatitis B or C are covered.
- E. For a properly preauthorized patient, benefits may be allowed for medically necessary services and supplies related to CLKT for:
- 1. Evaluation of a potential candidate's suitability for CLKT whether or not the patient is ultimately accepted as a candidate for transplantation.
 - 2. Pre- and post-transplant inpatient hospital and outpatient services.
 - 3. Pre- and post-operative services of the transplant team.
- 4. The donor acquisition team, including the costs of transportation to the location of the donor organ and transportation of the team and the donated organ to the location of the transplantation center.
- 5. The maintenance of the viability of the donor organ after all existing legal requirements for excision of the donor organ have been met.
 - 6. Blood and blood products.
- 7. FDA approved immunosuppression drugs to include off-label uses when determined to be medically necessary and in accordance with nationally accepted standards of practice in the medical community, (i.e., proven).
- 8. Complications of the transplant procedure, including inpatient care, management of infection and rejection episodes.
 - 9. Periodic evaluation and assessment of the successfully transplanted patient.
- F. Benefits are allowed for Hepatitis B and pneumococcal vaccines for patients undergoing transplantation.
- G. Benefits may be allowed for DNA-HLA tissue typing in determining histocompatibility.

III. POLICY CONSIDERATIONS

- $\mbox{\sc A.}\,$ Preauthorization and retrospective authorization of CLKT must meet the following two requirements:
- 1. Patient meets (or as of the date of transplantation would have met) patient selection criteria; and
- 2. Transplant facility is (or as of the date of transplantation would have been) TRICARE or Medicare approved for liver transplantation at the time of transplantation.

- B. In those cases where the beneficiary fails to obtain preauthorization, benefits may be extended if the services or supplies otherwise would qualify for benefits but for the failure to obtain preauthorization. If preauthorization is not received, the appropriate preauthorizing authority as outlined in paragraph II.A. under Policy is responsible for reviewing the claims to determine whether the beneficiary's condition meets the clinical criteria for the CLKT benefit. Charges for transplant and transplant-related services provided to TRICARE Prime enrollees who failed to obtain PCM referral and HCF authorization will be reimbursed only under Point of Service rules.
- C. Benefits will only be allowed for transplants performed at a TRICARE or Medicare approved liver transplantation center. The contractor in whose jurisdiction the center is located is the certifying authority for TRICARE approval as a liver transplantation center. Refer to Chapter 11, Section 11.5 for organ transplant certification center requirements.
- D. Claims for services and supplies related to the transplant will be reimbursed based on billed charges.
- E. Claims for transportation of the donor organ and transplant team shall be adjudicated on the basis of billed charges, but not to exceed the transport service's published schedule of charges, and cost-shared on an inpatient basis. Scheduled or chartered transportation may be cost-shared.
- F. Benefits will be allowed for donor costs. Refer to Chapter 3, Section 1.6L for guidelines regarding donor costs associated with organ transplants.
- G. Charges made by the donor hospital will be cost-shared on an inpatient basis and must be fully itemized and billed by the transplant center in the name of the TRICARE patient.
- H. Acquisition and donor costs are not considered to be components of the services covered under the DRG. These costs must be billed separately on a standard UB-92 claim form in the name of the TRICARE patient.
- I. Transportation of the patient by air ambulance may be cost-shared when determined to be medically necessary. Reference Chapter 7, Section 2.1.
- J. For beneficiaries who reside in TRICARE regions, the issuance of a Nonavailability Statement (NAS) shall be in accordance with direction of the Lead Agent.
- K. When a properly preauthorized candidate is discharged less than 24-hours after admission because of extenuating circumstances, such as the available organ is found not suitable or other circumstances which prohibit the transplant from being timely performed, all otherwise authorized services associated with the admission shall be cost-shared on an inpatient basis, since the expectation at admission was that the patient would remain more than 24 hours.

COMBINED LIVER-KIDNEY TRANSPLANTATION

IV. EXCLUSIONS

Combined liver-kidney transplantation is excluded when:

- A. The following contraindications exist:
- 1. Significant systemic or multisystemic disease (other than hepatorenal failure) which limits the possibility of full recovery and may compromise the function of the newly transplanted organs.
 - 2. Active alcohol or other substance abuse.
 - a. Benefits may be allowed if:
- (1) The patient has been abstinent for at least six months prior to transplantation; and
- (2) There is \underline{no} evidence of other major organ debility (e.g., cardiomyopathy).
- (3) There is evidence of ongoing participation in a social support group such as Alcoholics Anonymous; and
 - (4) There is evidence of a supportive family/social environment.
- 3. Malignancies metastasized to or extending beyond the margins of the liver and $\!\!/$ or kidney.
 - B. For:
- 1. Expenses waived by the transplant center, (i.e., beneficiary/ sponsor not financially liable.)
- 2. Services and supplies not provided in accordance with applicable program criteria, (i.e., part of a grant or research program, unproven procedure).
- 3. Administration of an unproven immunosuppressant drug that is not FDA approved. Refer to Chapter 7, Section 7.3 for Policy requirements for immunosuppression therapy.
- 4. Pre- or post-transplant nonmedical expenses (i.e., out-of-hospital living expenses, to include, hotel, meals, privately owned vehicle for the beneficiary or family members).
 - 5. Transportation of an organ donor.

V. EXCEPTIONS

A. Services and supplies for inpatient or outpatient services that are provided prior to and/or after discharge from hospitalization for a CLKT performed in an unauthorized TRICARE or Medicare liver transplantation center may be cost-shared subject to applicable

Program policy. Pre-admission services rendered by an unauthorized transplant center may also be cost-shared subject to applicable program policies. These exceptions are also applicable to CLKTs performed prior to the effective date of November 12, 1992.

- B. CLKTs performed on an emergency basis in an unauthorized liver transplant facility may be cost shared <u>only</u> when the following conditions have been met:
- 1. The unauthorized center <u>must</u> consult with the nearest TRICARE-authorized liver transplantation center regarding the transplantation case; and
- 2. It must be determined and <u>documented</u> by the transplant team physician(s) at the authorized liver transplantation center that transfer of the patient (to the authorized liver transplantation center) is not medically reasonable, even though transplantation is feasible and appropriate.
- C. This policy does not apply to beneficiaries who become eligible for Medicare coverage due to <u>isolated</u> renal disease (refer to <u>Chapter 9</u>, <u>Section 2.2</u>). This policy applies only to those individuals suffering from concomitant hepatic <u>and</u> renal failure. Coordination of benefits with Medicare is not required for CLKTs.

VI. EFFECTIVE DATE

- A. November 12, 1992.
- B. November 1, 1994, for hepatitis C.
- C. December 1, 1996, for hepatitis B.

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